UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re Bair Hugger Forced Air Warming Products Liability Litigation	MDL No. 15-2666 (JNE/FLN)
This Document Relates to All Actions	**PLAINTIFFS' OBJECTION TO THE RULING OF THE MAGISTRATE JUDGE ON PLAINTIFFS' MOTION TO AMEND THE MASTER LONG FORM COMPLAINT AND MASTER SHORT FORM COMPLAINT TO ASSERT A CLAIM FOR PUNITIVE DAMAGES**

Pursuant to Local Rule 72.2(a)(3), Plaintiffs respectfully file this objection to the July 27, 2017 ruling of the Magistrate Judge (Doc. No. 629) regarding Plaintiffsô Motion seeking leave to amend the Master Long Form and Master Short Form Complaints to Add a Claim for Punitive Damages (Doc. No. 307). The Magistrate Judge denied Plaintiffs Motion to Amend as futile. In particular, the Order held that plaintiffsô allegations with regard to Defendantsô knowledge of contamination and patient risk were ñthreadbare recital[s] of the knowledge element of the statute.ò Respectfully, the Order overlooks specific, factual allegations concerning Defendantsô knowledge of Bair Hugger contamination, along with the impact the Bair Hugger has on the airflow in the operating room, and the alleged resultant elevated risks to patients caused by these defects. The Magistrate Judgeôs ruling was clearly erroneous and contrary to law, and the Plaintiffs therefore respectfully file this Objection to the Order pursuant to Local Rule 72.2(a)(3), and dutifully request that the Court allow Plaintiffsô motion to amend.

LEGAL STANDARD

A. Legal Standard for Review of Magistrate's Order.

Within fourteen days after being served with a copy of a magistrateôs order, a party may serve and file objections to the order. LR 72.2(a)(3). The district judge ñmust consider timely objections and modify or set aside any part of the order that is clearly erroneous or is contrary to law.ò LR 72.2(a)(3); s*ee also* 28 U.S.C. § 636(b)(1). This objection is being filed within fourteen days after being served with a copy of the magistrateôs order, and is accordingly, timely.

A motion to amend should be denied as futile only where the amended complaint would not withstand a motion to dismiss under Rule 12(b)(6). *See In re Senior Cottages of America, LLC*, 482 F. 3d 997, 1001 (8th Cir. 2007). At this stage, Plaintiffs factual allegations must be accepted as true. *Id*. Plaintiffs are entitled to all reasonable inferences. *Brown v. Green Tree Servicing LLC*, 820 F. 3d 371, 373-374 (8th Cir. 2016). The Court must evaluate the plausibility of Plaintiffsô allegations collectively, and should not evaluate individual allegations in isolation. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322-12 (2007).

The Order appears to cast doubt of the viability of Plaintiffsô claim, specifically Plaintiffsô allegations that Defendants had knowledge of the facts as required by Minn. Stat. § 549.20. But denying the motion to amend as futile is not the proper vehicle to test the *strength* of Plaintiffsô proof. ñ[A] well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of the facts alleged is improbable, and óthat a recovery is very remote and unlikely.ôò *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556

(2007) (*quoting Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974)). Plaintiffs identified specific people with specific knowledge of specific dangers associated with Bair Hugger. Taken alone or together, Plaintiffsô allegations demonstrate Defendantsô deliberate disregard for the rights or safety of others, and accordingly, the motion for leave to add a claim for punitive damages should be granted.

ARGUMENT

Plaintiffs have alleged facts that demonstrate Defendantsô knowledge that Bair Hugger devices could harbor and spread bacteria into the air in an operating room, placing patients at risk of infection as a result of airborne bacteria. Defendants knew of that risk for years ï indeed the risk of bacteria becoming aerosolized was known and warned about when the Bair Hugger device was first manufactured and sold by Augustine Medical[1] - yet, as Plaintiffs have alleged, Defendants [redacted]. Plaintiffs have also alleged in our proposed Second Amended Master Long Form Complaint that Defendants have engaged in a campaign to belittle and smear peer-reviewed papers showing that Bair Hugger increased the risk of surgical site infections.

Plaintiffsô proposed amendment did not rely on mere conclusions to establish Defendantsô knowledge that Bair Hugger devices were contaminated with bacteria. Each

[1] See Ex. 9 to Doc. No. 315.

of the following factual allegations are made in Plaintiffs' Proposed Second Amended Master Long Form Complaint (Doc. No. 308), and each of these allegations provide plausible support for Plaintiffs' contention regarding Defendants' knowledge that Bair Hugger devices were contaminated:

- [redacted]
- [redacted]
- [redacted]
- ¶ 47 (describing peer-reviewed publication finding presence of viable microorganisms in 100% of Bair Hugger devices); see also [redacted]
- ¶ 239 (alleging Defendant knowledge of Bair Hugger contamination via review of peer-reviewed article)

In addition, it is reasonable to infer from many of the other allegations offered in Plaintiffs' Proposed Second Amended Master Long Form Complaint that Defendants had such knowledge. For example, [redacted]. *See* Proposed Amended Complaint at ¶¶ 226-230. In sum, there are ample, specific allegations in Plaintiffs' Proposed Amended Complaint that Defendants knew that Bair Hugger devices were full of bacteria.

Insofar as it focuses only on patient injuries arising from bacterial colonies growing inside of Bair Hugger devices, the Order appears to apply an unnecessarily narrow scope to Plaintiff's punitive damages allegations. However, Plaintiffs have alleged multiple means by which Bair Hugger increases the risk of surgical site infection. One allegation of defect is through the contamination of Bair Hugger heaters and hoses. A separate allegation of defect relates to insufficient filtration of air entering the Bair Hugger device. Put simply, Defendants knew that Bair Hugger can suck up and expel microbes into the operating room because Defendants' devices are not adequately filtering them. Plaintiffs' established Defendants' knowledge of the need to filter microbes from incoming air through at least the following allegations:

- ¶53 – referencing a June 1997 letter to the FDA in which Defendants admit filter efficiency is related to prevention of microbial wound contamination.
- [redacted]
- [redacted]
- [redacted]

Finally, Plaintiffs also alleged in our Proposed Amended Master Long Form Complaint that the Bair Hugger is defective because Defendants knew that Bair Hugger disrupted laminar airflow in operating rooms and that such disruption increased the risk of surgical site infections. The following factual allegations were made in support this contention:

- ¶241 ï alleging that defendants had knowledge of the McGovern study, which describes mobilization of unsterile air from the floor of the operating room to the surgical site, and further describing an elevated risk ratio of 3.8 when the Bair Hugger was used compared to the free-warming period

- ¶209 ï alleging that operation of a Bair Hugger in an operating room does, in fact, result in mobilization of particles on or near the floor to the surgical site.

The Order also held that Plaintiffs allegations that Defendants had knowledge of the patient safety risk were merely conclusory. Order at 16. But Plaintiffs did not merely parrot the language of § 549.20. Instead, Plaintiffs presented detailed allegations establishing that Defendants knew Bair Hugger presented a surgical site infection safety risk. Plaintiffs proposed the following allegations that provide factual support for our contention that 3M had actual knowledge of potential patient safety risks:

- ¶53: ñIn a June 1997 letter to the FDA, for example, Defendants admitted that ñair blown intraoperatively across the surgical wound may result in airborne contamination.ò That admission was made in a section of the document titled ñSummary of Safety,ò and specifically references measures to prevent ñmicrobialò contamination. Defendants knew that microbial contamination was (as Defendantôs own submissions to the FDA describe it), a ñsafety issue.ò [FN ï characterizing the filter efficiency and risk of airborne contamination as a ñsafety issueò remained part of 510k submissions at least through the Model 750, where Defendant represented to the

FDA "[t]he Model 750 filter is more effective than the Model 505 filter." https://www.fda.gov/cdrh/510k/K001149.pdf at 42.]

- [redacted]
- ¶ 267 – prior versions of the Bair Hugger warned of the risk of airborne contamination, as do competitive devices known to 3M, such as the Stryker Mistral-Air Plus.
- [redacted]
- [redacted]
- ¶ 241 (Alleging 3M's knowledge of a study that showed bacteria being delivered to a surgical site); see also ¶ 242 (additional allegation of 3M's knowledge of the McGovern study, among others). Importantly, the study in ¶ 241 identifies an elevated risk ratio of 3.8 when the Bair Hugger was in use compared to the air-free warming period.
- [redacted]

[redacted]

[redacted] In particular, Defendants knew that blowing air around a surgical suite increased the risk that bacteria

would be mobilized and end up in the surgical site. Knowledge of that risk goes all the way back to the 1997 FDA letter identifying 0.2 micron filtration along with a tape barrier as a means of preventing such infections. [redacted]. Again, taken as a whole, Plaintiffs have offered allegations sufficient to support a claim for punitive damages.

The Order appears to substantially increase Plaintiffs' burden at this pleading stage by requiring proof that the presence of bacteria in the Bair Hugger would result in an increased risk of the surgical site. First, as described in the allegations below, Plaintiffs adequately pled that Defendants were aware of that risk.

- [redacted]
- ¶ 239 the Albrecht study specifically found that forced air warming devices generated airborne contamination as a result of microorganism growth on internal air path surfaces, and identified the risk that such contamination could settle onto the surgical site.
- [redacted] see also ¶ 242 (additional allegation of 3M's knowledge of the McGovern study, among others).
- [redacted]

Second, Plaintiffs have alleged in many instances the connection between internal

contamination and surgical site infection, see, e.g., ¶¶ 7, 14, 38, 50, and 73(b). In addition, the 2009 Albrecht study specifically warned that the mobilization of microorganisms increased the risk of surgical site infection. *See* ¶ 239.

The Order notes that none of the peer-reviewed papers provide a definitive causal connection between airborne contaminants in the Bair Hugger and surgical site infections. But even if none of these peer-reviewed papers taken on itôs own reaches the ultimate conclusion with respect to Plaintiffsô allegations, that is not determinative of Defendantsô knowledge of the underlying allegations required to sustain Plaintiffsô case at the pleading stage. Plaintiffs surely understand that at trial, Plaintiffs must prove causation. But not in the pleadings.

Evaluating the strength of the partiesô respective proof is simply not appropriate in considering a motion to amend. At this stage, Plaintiffs need only provide plausible allegations, not rule out every other potential explanation. ñRequiring a plaintiff to rule out every possible lawful exception for the conduct he challenges would invert the principle that the ócomplaint is construed most favorably to the nonmoving party,ô and would impose the sort of óprobability requirementô at the pleading stage which *Iqbal* and *Twombly* explicitly reject.ò *Braden v. Wal-Mart Stores, Inc.*, 588 F.3d 585 at 597 (internal citations omitted).

Here, Plaintiffs have shown that Defendants were aware that microbial contamination increased the risk of surgical site infection. [redacted] k. Additionally, Albrecht raised that specific risk in the 2009 paper. Defendants were aware of that paper and sent a letter trying to

assuaging customersô concerns. [redacted]

[redacted].

Defendants may come up with some explanation for their consistent and ongoing failure to act, but it would be untimely and inappropriate to consider such explanations today in connection with a motion to amend the pleadings.

The Order rejected Plaintiffs contention that Defendants acted with deliberate indifference to the risk that patients would continue to be injured by surgical site infections as a result of 3Môs campaign of disinformation and suppression and refusal to warn of the risk of bacterial contamination. Defendants took no remedial action upon gaining knowledge of the risk of surgical site infections associated with the use of Bair Hugger. Indeed, they instead attacked the authors of various studies and generated their own self-serving studies. The effect of which is to encourage continued use of a product that causes devastating infections.

Plaintiffsô proposed amended complaint proposes specific factual allegations that demonstrate 3Môs deliberate indifference to the increased risk of surgical site infections:

- [redacted]
- [redacted]
- [redacted]

[redacted]

- [redacted]

These allegations, taken as true, demonstrate a concerted effort by Defendants to hide the risks associated with their device so that its customers will continue to buy and use it. The Court is required to proceed ón the assumption that all the [factual] allegations in the complaint are true[,ô] [e]ven if their truth seems doubtful.ò *Id*. at 185 (court's emphasis) (quoting *Twombly*, 550 U.S. at 556). Because the plaintiff is entitled to the benefit of the doubt, ñit is not the province of the court to dismiss the complaint on the basis of the court's choice among plausible alternativesò; rather, ñthe choice between or among plausible interpretations of the evidence will be a task for the factfinder,ò assuming that the plaintiff ñcan adduce sufficient evidence to support its factual allegations.ò *Id.* at 190. Accordingly, in light of the specific allegations made by Plaintiffs and the support provided in connection with our motion, Plaintiffsô Motion to Amend the Master Long Form Complaint and Master Short Form Complaint to Add Claim for Punitive Damages should be granted.

CONCLUSION

Plaintiffs respectfully object to the Order of the Magistrate Judge, and request the Court enter an order granting Plaintiffsô Motion to Amend the Master Long Form Complaint and Master Short Form Complaint to Add Claim for Punitive Damages.

Respectfully submitted,

Dated: August 10, 2017

/s/ Genevieve Zimmerman

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